EU Declaration of Conformity

The manufacturer:

Company: Pam Mobility s.r.l.

Address: Via Verdi, 39 - 42043 Gattatico (RE) - Italy

SRN: IT-MF-000027951

Declares, under its own and exclusive responsibility, that the device(s)

Code	Model	ID BD/RDM	BASIC UDI-DI
727T0045	Electric variable height bed	2322647/R	805577420727T0045VS
727T0045S	Electric variable height bed	2322649/R	805577420727T0045SZH
727T0045C	Electric variable height bed	2392251/R	805577420727T0045CYH

Intended use: The device is intended to be used in adult patient's diagnosis, treatment and monitoring, under a doctor's supervision.
Usage environment: application environment 2 or 3 according to CEI UNI EN 60601-2-52.
The bed cannot be used in potentially explosive or inflammable atmosphere.
People authorised to use the product: patient, specialised operators and doctors.

Risk class: Class I (in accordance with Rule 1, Annex VIII of Regulation (EU) 2017/745)

It complies with the following European Union legislative acts:

(EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) no. 178/2002 and Regulation (EC) no 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2006/42/EC	Directive 2006/42/EC of the european Parliament and of the Council, of 17 May 2006 on machinery, and amending Directive 95/16/EC
2014/35/EU	Directive 2014/35/EU of the european Parliament and of the Council, of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits
2014/30/EU	Directive 2014/30/EU of the european Parliament and of the Council, of 17 May 2006 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility
2011/65/EU	DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment with modification by the DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015

Complies with the following technical/harmonised standards and/or common specifications:

CEI EN 60601-1:2007 + EC:2010 + A11:2012 + A1:2014 + A12:2015 + A2:2022 - Apparecchi elettromedicali
Parte 1: Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali

CEI UNI EN 60601-2-52:2016 - Apparecchi elettromedicali
Parte 2: Prescrizioni particolari relative alla sicurezza fondamentale e alle prestazioni essenziali dei letti medici

The device is subject to the conformity assessment procedure provided for in article 52, section 7 of Regulation (EU) 2017/745

Gattatico,
27 april 2023

Managing Director
Andrea Muzzini

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